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K112210
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MEDICAL INTELLIGENCE MEDIZINTECHNIK GMBH

ELEKTA

Fraxion™ - 510(k) Summary

1.	Applicant:	Medical Intelligence Medizintechnik GmbH
2.	Address:	Robert-Bosch-Str. 8 86830 Schwabmünchen Germany
3.	Contact Person:	Mr. Michael Wolff Tel.: +49 (0)8232 9692-701
4.	Preparation Date:	July 20, 2011
5.	Device Submitted:	Fraxion™
6.	Proprietary Name:	Fraxion™
7.	Common Name:	Fraxion™
8.	Classification Name:	Accelerator, Linear, Medical
9.	Substantially Equivalence:	The Fraxion™ is substantially equivalent in terms of intended use to the following marketed devices: Elekta Esarte Frame System (K051746), Elekta Extend System (K092083), Medical Intelligence HeadFIX System (K030439).
10.	Device Description:	Fraxion™ is a device for cranial stereotactic radiotherapy and radiosurgery. The major parts of the system include the Fraxion frame, Patient Control Unit, Frontpiece incl. Mouthpiece, vacuum cushion, thermoplastic mask and Stereotactic Frame.
11.	Intended Use	Fraxion™ is intended to be used for immobilization, positioning and re-positioning during Stereotactic Radiotherapy (SRT) in all parts of the brain and head in a Linear Accelerator environment. Further Fraxion™ is used to immobilize and position the head during image acquisition to support treatment planning. Under certain circumstances (e.g. when the patient will not tolerate an invasive frame) Fraxion™ may also be used for Stereotactic Radiosurgery (SRS) in a Linear Accelerator environment.
12.	Legally-Marketed Predicated Device	Elekta Esarte Frame System, Elekta Extend System and Medical Intelligence HeadFIX System

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael Wolff
Regulatory Affairs Manager
Medical Intelligence Medizintechnik GmbH
Robert-Bosch-Strasse 8
86830 SCHWABMUENCHEN
GERMANY

NOV 22 2011

Re: K112210
Trade/Device Name: Fraxion™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 20, 2011
Received: August 1, 2011

Dear Mr. Wolff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112210

Device Name: Fraxion™

Indications for Use:

Fraxion™ is intended to be used for immobilisation, positioning and re-positioning during Stereotactic Radiotherapy (SRT) in all parts of the brain and head in a Linear Accelerator environment.
Further Fraxion™ is used to immobilise and position the head during image acquisition to support treatment planning.
Under certain circumstances (e.g. when the patient will not tolerate an invasive frame) Fraxion™ may also be used for Stereotectic Radiosurgery (SRS) in a Linear Accelerator environment.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112210